August 2, 2024

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Bucshon,

On behalf of the Association of Public and Land-grant Universities (APLU), thank you for the opportunity to comment on the future of 21st Century CURES Act. As you described in your “Dear Stakeholder” letter, this Act played a pivotal role in advancing biomedical research and innovation and supporting U.S. leadership in biomedical sciences.

APLU is a membership organization that fosters a community of university leaders collectively working to advance the mission of public research universities. The association’s U.S membership consists of more than 230 public research universities, land-grant institutions, state university systems, and affiliated organizations spanning across all 50 states, the District of Columbia, and six U.S. territories. The association and its members collectively focus on increasing advancing academic excellence, student success, and workforce readiness; promoting pathbreaking scientific research; and bolstering economic and community engagement. Annually, its U.S. member campuses enroll 4.3 million undergraduates and 1.3 million graduate students, award 1.25 million degrees, employ 1.2 million faculty and staff, and conduct $58 billion in university-based research.

The importance of biomedical research to the country is evidenced by the focus of three recent actions: your call for comments on the 21st Century CURES Act, the current Energy and Commerce Committee request for information (RFI) and FY 25 Labor-HHS- Ed bill language, which would both significantly reorganize the National Institutes of Health. For expediency, APLU will share similar policy suggestions and observations in response to the two RFIs. APLU’s key observations are bolded here and discussed more in-depth below:

- **Any future legislative effort should focus on supporting high-quality science, improving efficiency, accelerating medical progress, promoting the next generation of researchers and clinicians, and protecting U.S. competitiveness in the biomedical sciences.**
• NIH realignment should include a clearly defined process for considering informed stakeholder perspectives and a timely and transparent transition plan that provides operational clarity to researchers, research institutions, and patients and families.

• Congress should not support arbitrary limits on grants or reimbursements to the cost of doing research that could delay important research or harm U.S. competitiveness.

• APLU agrees it is imperative NIH and public research universities have clear and robust processes for addressing research misconduct.

• Congress should allow newly-created research security regulations and policies to be fully implemented, at NIH and other agencies, and for their impact to be evaluated before adding on additional measures that could hinder appropriate and mutually-beneficial international partnerships.

• Congress should ensure that any further regulations related to dual-use research of concern and pathogens with enhanced pandemic potential are complementary to new regulations that were published in May of 2024 and provide clarity across federal agencies and ensure long-term stability to oversight and risk management.

• Congress should extend authorization for the Research Policy Board to advise the federal government on the effects of federal research regulations and reporting requirements and recommend ways to modify, streamline and—most importantly—harmonize them across agencies.

National Institutes of Health Reorganization

As pointed out in the Energy and Commerce Committee NIH reform proposal, NIH has grown from its humble beginnings as a one-room laboratory to a world-leading agency that in FY 23 awarded $37.81 billion in research grants. These grants, in addition to supporting research that will lead to advances in human health supported 412,041 jobs and $92.89 billion in economic activity.\(^1\) Congress has been very active throughout that history in expanding the mission of the NIH through the establishment of 27 Institutes

\(^1\) UMR-NIHs-Role-in-Sustaining-the-US-Economy-2024-Update.pdf (unitedformedicalresearch.org)
and Centers to drive breakthrough medical innovations that enhance the quality of life and save millions of lives.

Overall, it is important to establish common goals for any reimagining of NIH structure or operations. Any future legislative effort should focus on supporting high-quality science, improving efficiency, accelerating medical progress, promoting the next generation of researchers and clinicians, and protecting U.S. competitiveness in the biomedical sciences.

It is appropriate to examine the number of Institutes and Centers and look for ways to make NIH’s administrative functions more efficient. However, the process of realignment must take into account researcher and patient perspectives, scientific convergence, and the current practice of medicine. The National Institutes of Health (NIH) Reform Act of 2006 included the creation of a Scientific Management Review Board (SMRB) to help advise the NIH director on Institute and Center organization, structure, and management. While the Energy and Commerce Committee report points to its lackluster results, the SMRB concept could be reinvigorated and strengthened to help guide a process that will include board stakeholder input and deep scientific thought.

In addition, any consolidation should be conducted in a phased approach that provides clarity for grantees. NIH awards 60,000 grants that directly support 300,000 researchers at more than 2,500 different institutions. Consolidation without clear administrative plans and instructions for researchers and institutions would cause confusion and possibly disruptions for the millions of patients participating in the 502,222 cutting-edge clinical trials supported by NIH. Significant consolidation of Institutes and Centers should not be done in a one-year appropriations cycle.

**National Institutes of Health Financial Stability to Support Innovation**

The CURES Act helped spur important new cross-disciplinary and cross-NIH initiatives including ALL of US, the Brain Initiative, the Cancer Moonshot, and the Regenerative Medicine Innovation Project through the use of a mandatory funding mechanism to supplement NIH appropriations. Unfortunately, due to the limitations imposed by recent budget agreements, Congress has not been able to maintain all funding beyond the CURES timeline. The result is a dangerous budget cliff for some programs.

NIH can only currently afford to fund one in five research proposals. While efficiencies can likely be found in many areas, ultimately NIH’s long-term success in saving lives and supporting our nation’s international and economic leadership requires consistent and robust annual growth through appropriations. Any financial savings that may result from proposed consolidated Institutes and Centers should be reinvested into world-leading biomedical and clinical research through NIH.
APLU urges partnership between congressional authorizers, appropriators, and the biomedical research community to support long-term sustainable funding growth to support NIH. Repealing the authorization for the Public Health Service (PHS) Evaluation Set-Aside would have a significant impact on current operations of certain Institutes and Centers. For instance, the PHS set-aside currently provides a significant portion of funding for the National Institute of General Medical Sciences used for R01 awards and the IDeA program, which is designed to improve the competitiveness of investigators in states that historically have not received significant levels of NIH research funding. Authorizers and appropriators should work together to ensure smooth budgeting transitions to avoid inadvertent harm.

**Grant Policies**

**Government-University Partnership**

The partnership between the federal government and research universities that emerged out of World War II is a significant reason our country is the envy of the world and the global innovation leader. This partnership – whereby the federal government, through competitively awarded grants, funds research that universities conduct on behalf of the nation – has yielded major scientific advances, including tremendous improvements in human health, and has trained America’s most prominent scientists, engineers, and entrepreneurs. It has also fueled economic growth in every corner of the country.

Recognizing that institutions incur essential research expenses that may not be directly attributable project by project, the government has included facilities and administrative (F&A) reimbursements in federal grants since the 1940s. Some of the most commonly cited examples of these F&A costs are utilities such as heat, lighting, water, and power needed to operate a lab, but F&A costs cover much more.

Research funded by NIH often relies on the use of extensive tissue and sample collections, and scores of professionals to ensure compliance with the plethora of complex federal, state, and local regulations on human and animal subject research protections, privacy, health, and safety, and for management and technical support. All these F&A costs are essential research costs. In fact, a recent report by the Council on Government Relations (COGR) cataloged a 172 percent increase in new regulations, new policies, or modified regulations impacting federal research in the last ten years. No entity – not universities nor industry nor the government itself – could conduct quality research without incurring these important research infrastructure expenses.

Universities are not close to being fully reimbursed for the expenses they incur to provide the necessary infrastructure and support to conduct federally supported research. According to data collected by the National Science Foundation (NSF), in FY20 universities contributed approximately $5.7 billion in facilities and administrative expenditures not reimbursed by the government. In addition, the Office of Management
and Budget (OMB) specifically limits how much universities can be reimbursed for administrative costs, even as required administrative responsibilities continue to increase due to new federal security requirements and other regulatory changes. In fact, since that OMB administrative cost limit was established in 1991, over 200 new federal policies have been implemented or revised, adding significant new costs for institutions participating in federal research programs.

The considerable risks of underinvestment in basic research infrastructure are evident elsewhere in the research enterprise. A 2021 study focused on buildings and supporting facilities at colleges and schools of agriculture that are authorized to receive USDA NIFA funding. USDA funding is capped at a lower rate than other agencies. The study found that the deferred maintenance estimate across the 97 colleges and schools of agriculture institutions surveyed is $11.5 billion and 69% of the infrastructure at those colleges and schools of agriculture are over 25 years old. Congress should be cautious of the impacts of arbitrary caps on F&A rates and potential unintended consequences.

The process by which the federal government and institutions negotiate F&A rates is rigorous and complex. It is based on an extensive information collection that includes the age and condition of facilities and buildings, maintenance, utilities, and administration costs that may vary by institution and region (payroll, accounting, or information technology). Caps or reductions in F&A rates would lead to the deterioration of research facilities and capabilities and limit participation in biomedical research to only the most well-resourced institutions.

This would have downstream impacts on the preparation of the biomedical workforce and the contribution to the economy in the regions with fewer well-resourced institutions. Such an outcome would run counter to the federal priorities to broaden participation in research by under-resourced and geographically diverse institutions. The United States cannot afford to hamper its research enterprise at a moment when our global competitors are massively ramping up investment in their research enterprise, including world-class research facilities.

Limiting grants to researchers

As a critical component of the research pipeline, providing more opportunities for early career researchers should be an important goal of any NIH realignment. However, the proposed limit of three ongoing NIH grants does not address the needs of early career researchers and could harm important ongoing and emerging research.

It is important to point out that a vast majority of the thousands of primary investigators that received funding from NIH only have one grant. For those with more than one grant, there is often an overlap of a time where one grant is ending and other is beginning. A strict three-grant limit could prevent the pursuit of grants to continue a fruitful research program as earlier grants are in their final years, leading to a cliff of
support that would prevent both young and old labs from building momentum. Second, the limit does not take into consideration grant size. Under the Energy and Commerce Committee’s proposed framework, a PI’s portfolio of three small grants or extensions would be viewed the same as three large awards, potentially discouraging researchers from pursuing innovative new ideas. Finally, a cap on the number of awards could discourage or outright prevent the pursuit of programs related to emerging crises, impacting our nation’s ability to address new threats to public health.

APLU shares the goal of supporting early career researchers and is interested in exploring alternatives to the proposed award cap. For example, current NIH policies prevent PIs from reducing themselves below 25% of their originally proposed time of work on a grant. This is a clear barrier to the handing off of in-progress grants to the next generation. NIH grant structures and mentorship requirements can be examined for further opportunities for early career researchers to be PIs on grants.

**Combatting Harassment**

APLU agrees it is imperative NIH have clear and robust processes for addressing misconduct. Addressing research misconduct ensures that public research universities have trustworthy and reliable science. Addressing sexual, gender, and all other forms of harassment is critical for ensuring safe and inclusive research labs and a diverse STEM workforce. Congress recognized the importance of this issue by including the Combating Sexual Harassment in Science Act in the CHIPS and Science Act in 2022.

Given these imperatives, we support NIH having the oversight ability to suspend funding for researchers for an appropriate period of time if there is an institutional finding of research misconduct or sexual harassment. Additionally, we support NIH’s need for clear, robust processes to address misconduct, including the ability to share findings from completed investigations of research misconduct and sexual harassment.

NIH strengthened its sexual harassment policies and procedures based on community input, particularly recommendations from the NIH Advisory Committee to the Director’s *Changing the Culture to End Sexual Harassment* (2019) report. The adoption of some of these recommendations can be seen in current NIH policies, as outlined in OSTP’s recent *Inventory of Policies, Procedures, and Resources Related to Preventing and Responding to Sex-Based and Sexual Harassment* (2024).

One recommendation Congress should consider from the NIH report, that has not yet been implemented, is Recommendation 1.6. This recommendation would require that PIs and key personnel for NIH grants and contracts attest they have not violated their institution’s code of professional conduct, and it would require that the institution’s grants administration office confirm there are no findings of professional misconduct for senior personnel. For grant transfers, it would require attestations from the researcher and the institution that the researcher is not under investigation and has no
professional misconduct findings. The recommendation also encourages NIH to develop an internal procedure for reviewing disclosures, which should include a conversation with the grantee institution about the nature of the findings and any institutional actions taken. If these recommendations were adopted and implemented, it would decrease the opportunity for bad actors to move between institutions.

**Protecting Federal Research Investments**

*Research security*

The U.S. innovation ecosystem is the envy of the world, which is why foreign governments may attempt to take advantage of our open and collaborative research ecosystem. Public institutions recognize they have a responsibility to protect federal R&D investments. APLU worked with federal agencies (including NIH) and our member institutions to identify and share best practices to help protect against foreign government interference, influence, and theft of research and innovative discoveries. In furtherance of securing research, APLU surveyed our member universities on research security practices, held work sessions to advance best practices in the field and further understanding of the problems that must be addressed, and hosted numerous federal agency officials at association meetings to enhance collaboration between the academic and security agency communities. While increasing research security measures, public universities are simultaneously working to ensure they remain open and inviting to attract the best minds and ideas throughout the world.

Since 2018, NIH has significantly increased its oversight in the area of research security. NIH was the first federal agency to make translated copies of concerning Chinese government “Thousand Talent” contacts public so institutions could better identify problematic behaviors. NIH implemented new policies regarding peer review, disclosure of foreign financial interests, financial conflicts of interests, and reporting on international partnerships. Universities stepped up by changing campus policies, providing better training for faculty, and creating more unified systems for tracking international partnerships. As a result of these actions, Michael S. Lauer, M.D. Deputy Director for Extramural Research, National Institutes of Health indicated in recent testimony before the House Science Committee that “Since 2020, the number of new allegations of undue foreign interference have substantially declined, and most have come from self-disclosures on the part of universities discovering problems on their own.2”

Congress has already passed extensive legislation requiring new faculty and institutional discloses of foreign gift, contracts, and relationships; new risk-based reviews for federally-funded research projects at DOD and other agencies; banning participation in

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2 Testimony-House-Foreign-Interference-2024.pdf (nih.gov)
malign foreign talent programs and Confucius Institutes; and many others. The CHIPS and Science Act has over half a dozen new research provisions that are still being implemented. It is also important to note that new common biosketch and disclosure forms for federal grant applicants, called for in National Security Presidential Memorandum-33 (NSPM–33) are just being adopted by all federal agencies. Additionally, new guidance on required institutional “research security programs” also called for in NSPM-33 were just released by OSTP last month.

Congress should allow newly-created research security regulations and policies to be fully implemented, at NIH and other agencies, and for their impact to be evaluated before piling on additional measures.

**Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential**

Effective biosafety and biosecurity practices are critical components of protecting human health and promoting consumer trust in scientific endeavors. In May, the White House Office of Science and Technology Policy (OSTP) published a comprehensive federal oversight framework “for conducting and managing certain types of federally funded life sciences research on biological agents and toxins.”

OSTP also published an implementation guide for agencies and researchers. The new framework will require significant new regulatory compliance and risk mitigation planning for researchers and institutions involved in life sciences research. Implementation of this framework is ongoing. Congress should ensure that any further regulations are complementary to this ongoing work, provide clarity across federal agencies, and ensure long-term stability to oversight and risk management.

**Regulatory Reform**

As indicated previously, the growing cost of compliance with federal regulations is taking away valuable resources from research and education. According to the Federal Demonstration Project 2018 study, primary investigators estimate that an average of 44.3 percent of their research time associated with federally-funded projects was spent on meeting requirements rather than conducting active research.

One of the core recommendations made in the 2016 National Academies report “Optimizing the Nation’s Investment in Academic Research: A new regulatory framework for the 21st century” and subsequently included in the 21st Century CURES Act, was the creation of a Research Policy Board. Specifically, the language in the CURES Act directed OMB to establish the Research Policy Board and envisioned a process to include federal employees, university representatives, and university-affiliated non-profit organizations. In addition to the CURES Act, 2016’s American

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3 [USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf (whitehouse.gov)](https://whitehouse.gov)
Innovation and Competitiveness Act also called for an Interagency Working Group on Research Regulation “for the purpose of reducing administrative burdens on federally funded researchers while protecting the public interest through the transparency of and accountability for federally funded activities.”

Unfortunately, all past legislative action has resulted in little action from OMB. The Government Accountability Office followed up with a 2021 report recommending Congress extend authorization for the Research Policy Board. Therefore, APLU remains supportive of the creation of a Research Policy Board to advise the federal government on the effects of federal research regulations and reporting requirements and recommend ways to modify, streamline and—most importantly—harmonize them across agencies.

We appreciate the opportunity to provide feedback and look forward to working with you to build a stronger NIH for the future. Please do not hesitate to contact me or APLU’s Vice President for Research Policy and Advocacy, Deborah Altenburg, if we can be of assistance.

Sincerely,

Mark Becker
President, APLU